5. 510 (K) SUMMARY

K062314

510 (k) SUMMARY
(per 21 CFR §807.92)

HORUS Laser Keratome

DEC 2 2 2006

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec AG Göschwitzer Strasse 51-52 07740 Jena Germany Est. Reg. No. 9615030
Contact Person:	Michael Giebe RA-Manager
U.S. Designated Agent:	Kent W. Jones Vice President, RA/CA/Compliance Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4353 (phone) (925) 557-4481 (fax)
Classification name:	Keratome
Classification:	Class II (acc. 21 CFR 878.4810)
Product Code:	GEX (21 CFR 878.4810) HNO (21 CFR 886.4370)
Trade/Proprietary name:	Horus

PREDICATE DEVICE

Company:	IntraLase Corporation
Device:	IntraLase FS Laser (K013941)
Company:	Bausch & Lomb Surgical
Device:	Hansatome Microkeratome (K010260)

INTENDED USE

The Horus Laser Keratome is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

DEVICE DESCRIPTION

The Horus Laser Keratome is a precision ophthalmic surgical laser designed for use in performing lamellar corneal resections. The cutting action of the Horus Laser Keratome is achieved through precise individual mirco-photodisruptions of tissue, created by tightly focused ultrashort pulses which are delivered through a disposable applanation lens while fixating the eye under very low vaccum.

SUBSTANTIAL EQUIVALENCE

The Horus Laser Keratome has technological characteristics very similar to those of the IntraLase FS Laser, the laser predicate device, while the indication for use and the intended use are identical to those of the Hansatome Microkeratome.

SUMMARY

The Horus Laser Keratome has been designed and tested to applicable safety standards. In addition, the Horus Laser Keratome was found to perform equivalently to the predicate device, the Hansatome Microkeratome, with respect to the creation of cornea resections in extensive ex-vivo studies.

A statement of substantially equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA stated: "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carl Zeiss Meditec, Inc.
c/o Kent Jones
5160 Hacienda Drive
Dublin, CA 94568

DEC 22 2006

Re: K062314
Trade/Device Name: Horus Laser Keratome
Regulation Number: 21 CFR 878.4310
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Codes: GEX; HNO
Dated: December 21, 2006
Received: December 22, 2006

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K062314

Device Name: Horus Laser Keratome

Indications for Use: The Horus Laser Keratome is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K062314

Prescription Use ✓
(Per 21 CFR 801.109)